

Remarks

This Amendment and Reply is filed in response to the final Office Action having a mailing date of January 2, 2003. Claims 15-34 are currently pending in the application with claims 15, 29, 30, 31 and 32 being in independent form. Claims 15-34 stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement. Claims 15-34 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. Claims 15, 19, 20, 23, 25 and 29-34 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Chaudhary* in view of *Bringman* and *Bram*. The Amendment filed March 19, 2001 is objected to under 35 U.S.C. §132 because the Examiner states it introduces new matter and has requested Applicants to cancel the amendatory material. Applicants will address each of these issues in the order presented in the Office action.

1. *35 U.S.C. §112, first paragraph*

The Examiner asserts that the specification does not reasonably provide enablement for a polypeptide encoded by a nucleic acid molecule 75% identical to SEQ ID NO:1 or 3. In sum, the Examiner states that it would require undue experimentation for the skilled artisan to practice the invention as claimed. In response, Applicants have amended the claims to recite 90% variants and incorporate the previous arguments of record as support. Support for the 90% variants may be found at page 6, line 7.

2. *35 U.S.C. §112, second paragraph*

The Examiner has rejected claims 15-34 under 35 U.S.C. §112, first paragraph on the basis that the specification does not reasonably provide enablement for "TACI" and "TACI-L." Applicants have amended the claims to delete reference to "TACI" and "TACI-L" and refer to the various polypeptides used in the screening assays in terms of amino acid sequences disclosed in SEQ ID NO:2 and 4.

Specifically, Claim 15 has been amended such that a protein (formerly TACI) comprises a polypeptide selected from the group consisting of: (a) the polypeptide of SEQ ID NO:2; (b) a fragment of the polypeptide of SEQ ID NO:2; or (c) a polypeptide encoded by a nucleic acid sequence that is at least 90% identical to SEQ ID NO:1; wherein said polypeptides and fragments of (i) (a), (b) and (c) bind SEQ ID NO:4. And, a second protein (formerly TACI-L) comprises a polypeptide selected from the group consisting of: (a) the polypeptide of SEQ ID NO:4; (b) a fragment of the polypeptide of SEQ ID NO:4; or (c) a polypeptide encoded by a nucleic acid sequence that is at least 90% identical to SEQ ID NO:3; wherein said polypeptides and fragments of (ii) (a), (b) and (c) bind SEQ ID NO:2. Claims 29-32 have been similarly amended.

Claims 16-28 have also been amended to delete reference to "TACI" and TACI-L." As such, all issues raised by the Examiner have been resolved and the rejections under 35 U.S.C. §112, second paragraph may be withdrawn.

3. 35 U.S.C. §103(a)

The Examiner has rejected claims 15, 19, 20, 23, 25 and 29-34 under 35 U.S.C. §103(a) as being unpatentable over *Chaudhary* in view of *Bringman* and *Bram* for reasons of record. Applicants respectfully traverse.

Applicants respectfully submit that the Patent Office has not set forth a *prima facie* case of obviousness because the cited art does not provide the requisite suggestion or motivation to combine the references. Applicants respectfully suggest that the Examiner has not viewed Applicants' invention as a whole and has inappropriately combined references that do not provide the requisite suggestion for the desirability of the combination.

The court in *In re Dembicza*k, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) stated that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See, e.g., *C.R. Bard*, 157 F.3d at 1352, 48 USPQ2d at 1232. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." E.g., *McElmurry v. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578, 27 USPQ2d 1129, 1131 (Fed. Cir. 1993).

It is well established that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Applicants respectfully submit that a conclusion of *prima facie* obviousness must be supported by *evidence*, a showing by some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references to arrive at the claimed invention. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). "A rejection cannot be predicated on the mere identificationof individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these

components for combination in the manner claimed." *In re Kotzab*, 217 F.3d 1365, 1369, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000).

The *Dembiczak* court further stated that a reference-by-reference, limitation-by-limitation analysis does not demonstrate how the prior art references teach or suggest their combination to yield the claimed invention. Also, the court in *In re Rouffet* reiterated the fact that "virtually all [inventions] are combinations of old elements." *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998), see also *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); and *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." *In re Rouffet, supra*, see also *Sensonics, Inc. v. Aerasonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996).

The claimed invention must be viewed as a whole. The claimed invention is a method of screening test compounds that affect the interaction of TACI and TACI-L. At the time of filing the present application, one of skill in the art did not know that TACI and TACI-L were cognates – this relationship was first discovered by Applicants. *Chaudhary* and *Bram* do not suggest in any way that their respective proteins specifically bind to the other. In April of 1999, one of skill in the art would have absolutely no basis to assume a nexus between TACI and TACI-L. As to the claimed invention, one of skill in the art in 1999 could not envision screening methods based on a specific receptor-ligand interaction until that specific receptor-ligand relationship has been elucidated (i.e., what is not known cannot be obvious). Certainly, one of skill in the art would not have a reasonable expectation of success in developing screening methods until the specific receptor:ligand pair was known.

Bringman has been cited to show that neutralizing antibodies, in the most generic sense, were known in the art. *Bringman* has no connection whatsoever to *Chaudhary* or *Bram*. The antibodies described in *Bringman* are not particular to TACI or TACI-L. There is no suggestion or motivation in *Chaudhary*, *Bram* or *Bringman* to combine the

prior art references to make the claimed invention. Therefore, the motivation to combine the references has been provided by the Examiner.

In addition, Applicants submit that part of the Examiner's reasoning is based on unsupported conclusory statements rather than clear and particular evidence required by the Federal Circuit. And, the Examiner has improperly shifted the burden of proof onto Applicants to show the Examiner's assumptions have a basis in fact. The Examiner assumes that the unidentified receptor on the BJAB cells described in *Chaudhary* is TACI and requires Applicants to prove otherwise. Applicants note that "The initial burden is on the Examiner to provide some suggestion of the desireability of doing what the inventor has done" (MPEP §2142). There is no evidence in any of the cited art that suggests the **specific** relationship between TACI and TACI-L and consequently there is no particular motivation to develop methods of screening based on TACI and TACI-L. With regards to the observation reported in *Chaudhary*, Applicants submit that merely showing that TACI-L (TNRL1- α) binds to a B-cell line (BJAB) does not unequivocally identify the TACI protein as the receptor for TACI-L, which is necessary to render the claimed invention obvious.

Applicants readily acknowledge that the claimed invention is to a certain extent a combination of elements already known in the art (i.e., TACI and TACI-L), but this is not sufficient grounds for finding obviousness ("virtually all [inventions] are combinations of old elements." *In re Rouffet, supra*). In general, the Examiner has found the individual elements of Applicants' claimed invention in the prior art, or at least prior art corollaries (i.e., *Bringman*). But, "[I]f identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention." *In re Rouffet, supra*). Applicants suggest this is precisely what has occurred.

Applicants respectfully submit that the only suggestion for the Examiner's combination of the isolated teachings of the applied references improperly stems from Applicants' disclosure. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). "Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of

the patented invention." *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998).

Finally, Applicants further note that a high level of skill in the art alone cannot be relied upon to provide motivation to combine prior art references in a manner that would render the claimed invention obvious. *In re Rouffet*, 47 USPQ2d 1453 (CAFC Jul. 15, 1998). The fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness. *Ex parte Levengood*, 28 USPQ2d 1300 (BPAI. 1993); MPEP 2143.01.

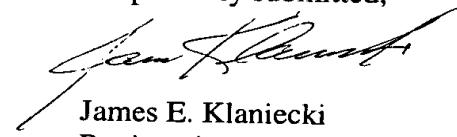
Based on the above arguments, Applicants respectfully request the rejection of claims 15, 19, 20, 23, 25 and 29-34 under 35 U.S.C. §103(a) be properly withdrawn.

4. 35 U.S.C. §132

The Examiner has objected to the amendment filed March 19, 2001 under 35 U.S.C. §132 for allegedly adding new matter. In response, Applicants have deleted the amendatory material as requested by the Examiner.

Applicants kindly request reconsideration and allowance of the pending claims. If any issues remain, the Examiner is cordially invited to call Applicants' representative to discuss resolution thereof.

Respectfully submitted,



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Signed: Nanci M. Kertson
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